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Development and Implementation of a Distance-Learning Certificate Program in Clinical Research Management at International Sites

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ABSTRACT

Researchers face growing challenges in implementing and managing clinical investigations, many of which are conducted at multiple national and international sites. There is a need to prepare individuals who can initiate, manage, and coordinate complex clinical studies, ensuring maintenance of high scientific and ethical standards and adherence to regulations stipulated by governmental and research funding agencies. Nurses and other health professionals who work as research coordinators or managers often lack formal educational preparation for their roles. Many of these individuals, particularly those who live in low-resource countries, do not have access to on-site training or education. This article describes the process used to develop, implement and evaluate distance-based certificate courses in coordination and implementation of clinical research for study coordinators and clinical research managers in Africa, Asia, Latin America, and the United States. Lock and Redmond proposed an online collaborative framework that could be used to facilitate the development of online courses and programs in international settings.[1] Key concepts in this model included: (a) developing and maintaining a teaching presence; (b) creating and sustaining a learning community; (c) scaffolding learning; (d) creating knowledge in action; (e) fostering social presence; (f) participating in critical discourse; and (g) exploring cognitive presence. The article describes the application of this framework to the development of our online courses for study coordinators and clinical research managers from sites across the globe. The article concludes with a description of key lessons learned and implications for future program development.

Keywords: clinical research coordinator, research training, international research, clinical research manager, distance-education, study coordinators

Development and Implementation of a Distance-Learning Certificate Program in Clinical Research Management at International Sites

Introduction

Researchers face growing challenges in implementing and managing clinical investigations, many of which are conducted at multiple national and international sites. There is a need to prepare individuals who can initiate, manage, and coordinate complex clinical studies, ensuring maintenance of high scientific and ethical standards and adherence to regulations stipulated by governmental and research funding agencies. Nurses and other health professionals who work as research coordinators or managers often lack formal educational preparation for their roles. Many of these individuals, particularly those who live in low-resource countries, do not have access to on-site training or education. This article describes the process used to develop, implement and evaluate distance-based

certificate courses in coordination and implementation of clinical research for study coordinators and clinical research managers in Africa, Asia, Latin America, and the United States. The program has evolved since its initial offering in 2005 based on experiences and data from needs assessments and evaluations. The article concludes with a description of key lessons learned and implications for future program development.

Review of Literature

Although there is growing recognition globally of the importance of the research coordinator or manager to the success of clinical research, there is a lack of consensus about the specific title, responsibilities, and training or certification requirements for this role. For the purpose of this paper, we use the term clinical research manager (CRM), although when discussing published research we use the terms used by the authors (such as clinical research coordinator, study coordinator, or research manager). The responsibilities of CRMs may include a variety of responsibilities depending on the specific study requirements. These responsibilities may include assisting with study planning, implementation, and reporting study findings. Other responsibilities associated with study planning may include conducting literature reviews, developing study protocols and standard operating procedures, recruiting and hiring project staff, and obtaining Institutional Review Board or Ethics Committee approval for the study. Responsibilities associated with project implementation may include recruitment and retention of study participants, advocacy, education of study participants and project staff, management and coordination of the research team, developing and managing the project budget, maintaining study protocols, standard operating procedures, and quality control, adhering to good clinical practice guidelines, and assisting with data management, and analysis. Responsibilities associated with the presentation of study findings may include preparing and giving presentations and press releases, as well as communicating results to project staff, participants, other members of the health team, sponsors, and regulatory bodies. [2-8,9-14]

Despite the complex responsibilities of the CRM, many CRMs receive only haphazard on-the-job training and many report feeling inadequately prepared for their roles. For example, Roberts, Rickard, Foote, and McGrail surveyed 49 ICU nurse research coordinators from Australia and New Zealand. These coordinators cited the lack of training opportunities, and the absence of a clear understanding of duties and responsibilities.[9] Hill and MacArthur surveyed 72 clinical research nurses in England and found that only half had received specific training for their roles.[7] Similar findings were reported by Anderson who found that most of the 55 study coordinators working in gene therapy trials surveyed received only on-the-job training, and 25% were dissatisfied with the training that they had received.[15] Silver documented a similar lack of training in the low-resource setting of South Africa, noting that a majority of clinical research staff, including investigators and study coordinators, received on-the-job training only.

Moreover, 60% of the research staff had not received specific training in research ethics.[16]

The Association of Clinical Research Professionals (ACRP) has offered certification since 1992, and the Society for Clinical Research Associates (SoCRA) has offered certification since 1995. However, there are no specific educational requirements for these certifications, and most research sponsors or hiring institutions do not require that their CRMs have certification. Several authors have identified the need to develop more clear guidelines for training and certification of CRMs. Mori, Mullen, and Hill, for example, recommended development of a certification exam for nurse research coordinators as a means of promoting accountability and improving the quality of clinical research.[8]

Providing appropriate and accessible education and training for CRMs is an ongoing dilemma. Because more clinical trials are being conducted in low-resource countries, it is critical to identify quality programs that are accessible to research personnel in these sites, and that are cost-effective.[17-21] Anderson suggested that minimal requirements for research coordinators include knowledge of conflict of interest and ethical issues, ensuring accuracy in data recording, and protecting study participants by identifying and reporting adverse events.[15] Silver described a comprehensive program to provide professional development and education for research coordinators in South Africa through the AERAS Global TB Vaccine Foundation and the South African Tuberculosis Vaccine Initiative (SATVI), located at the University of Cape Town, South Africa.[16] The goal of this program was to prepare qualified individuals to support clinical research efforts in South Africa. Shea, who works with the SATVI program, noted that although academic degree programs for clinical research training may be the ideal, in low-resource settings these programs are often inaccessible to study coordinators due to factors such as failure to meet admission requirements; inability to leave jobs to attend school because of the shortage of research personnel in study sites, and financial barriers (J. Shea, personal communication, August 7, 2008). One approach to addressing the failure of CRMs to meet program admission requirements is a pilot Saturday school program developed by SATVI to prepare students to pass university entrance exams and obtain a certification in basic clinical research. Although there have been no published reports evaluating this program, this program may serve as a model for other low-resource countries (J. Shea, personal communication, August 7, 2008).[16]

An approach to addressing the barriers related to program cost and difficulty leaving jobs to attend educational programs is the development of distance learning programs to train CRMs. Although a comprehensive review of literature about distance education is beyond the scope of this paper, numerous articles have been published identifying best practices and models for creating effective distance education courses.[2,22-26] Lock and Redmond proposed an online collaborative framework that could be used to facilitate the development of online

courses and programs in international settings.[1] Key concepts in this framework included: (a) developing and maintaining a teaching presence; (b) creating and sustaining a learning community; (c) scaffolding learning; (d) creating knowledge in action; (e) fostering social presence; (f) participating in critical discourse; and (g) exploring cognitive presence. We incorporated this framework in developing our online courses for study coordinators from sites across the globe.

Description of Program

This article reviews development and evaluation of distance-based courses on coordination of clinical research offered to CRMs at international sites, including sites in low-resource countries. The first course was funded by a grant from the HIV Prevention Trials Network (HPTN) (see www.hptn.org), and was offered in spring 2005 to 25 study coordinators working in HPTN sites in 11 countries. We subsequently received funding to offer the research coordination courses over a 2-year period (2006-2008) to 44 coordinators in Mali, Uganda, and India from the International Center for Excellence in Research (ICER). We received additional funding from the Center for Infectious Disease Research in Zambia (CIDRZ) to offer the courses to six study coordinators from that site from August 2007 to May 2008. In addition, in the summer of 2007 we offered a distance-based course in teaching strategies to a select group of participants in the initial research coordination courses. These participants subsequently served as co-teachers for the research coordination courses offered at their sites. The courses were offered in English, and participants were advised that a prerequisite was basic competency in written and spoken English. During the initial needs assessments, 85% to 100% of participants rated their level of reading, writing and speaking English as moderate to high. The Institutional Review Board of the University of Alabama at Birmingham approved the protocols for needs assessments and course evaluations.

Needs Assessments

Prior to offering the first course to the HPTN coordinators, we conducted a needs assessment in three phases. Initially we developed a survey tool based on a literature review, results from a focus group discussion at the 2005 HPTN annual meeting in Washington, D. C., and clinical research experiences of the authors. A needs assessment was then sent via E-mail to 63 coordinators from all 25 of the HPTN sites. After analyzing the survey data, we held an internet chat with the course faculty and two study coordinators at the HPTN sites in Peru and Zambia, to review and finalize plans for the course. We received survey responses from 21 coordinators in China , India, Malawi, Peru, South Africa, Tanzania, the U.S., Zambia, and Zimbabwe, for a 33% response rate . Respondents held a variety of positions including project study coordinator, research nurse, research officer, site coordinator, field coordinator, and project advisor. The respondents included physicians, nurses, pharmacists, and other health care workers. The majority of respondents indicated that they had a bachelor’s or master’s degree, but two

indicated that their highest level of education was a high school diploma. Participants had been working in clinical research from 1 to 10 years, and they had been working with the HPTN from 1 to 7 years. The needs assessment included a list of activities and topics related to research coordination. Respondents were asked to indicate whether they performed the activity in their jobs, and whether the topic should be included in the course.

Prior to initiating the ICER and CIDRZ courses, we revised the needs assessment tool based on feedback from the project team and from HPTN course participants. For the first year of the ICER-funded project, needs assessment surveys were sent via E-mail to study coordinators at the three ICER sites in India, Mali, and Uganda, and 24 responses were received. In the second year of the ICER-funded project, surveys were sent to a different group of study coordinators at the three sites, and responses were received from a total of 19 coordinators. For the CIDRZ-funded project in Year 3, surveys were distributed by CIDRZ staff to selected coordinators and responses were received electronically from 11 coordinators. The ICER survey coordinators included physicians, nurses, and other health care workers, and the CIDRZ coordinators included nurses and other health care workers. Items that were not included on the HPTN survey are marked as “NA.” There were 16 items in the original HPTN survey and 32 items in the revised surveys sent to ICER and CIDRZ coordinators. Table 1 illustrates findings from the three needs assessments. Consistent with reports from the literature, the findings indicate substantial variability in the responsibilities reported by respondents, but there was a high degree of interest in including content related to each of these responsibilities in the courses.

Table 1

Responses to HPTN, ICER, and CIDRZ Needs Assessment Surveys

Study Coordinator Responsibility	I do this in my job			Would like this included in education		
	HPTN	ICER	CIDRZ	HPTN	ICER	CIDRZ
1. Collecting and processing regulatory documents for a study	19	18	9	15	20	8
2. Interacting with the IRB (Ethics Committee)	16	17	10	14	19	8
3. Hiring, training and supervising research personnel	20	23	8	13	16	8
4. Data management issues	14	17	7	19	21	8
5. Study and site finances including study budgets	10	8	7	18	19	8
6. Managing study supply and	12	NA	NA	17	NA	NA

drug inventories						
7. Participant recruitment issues	16	17	9	13	18	8
8. Informed consent issues	13-15	17	11	12	20	7
9. Arranging and tracking study visits, activities and patients	19	13	8	12	15	6
10. Educating study participants on study activities	13	NA	NA	13	NA	NA
11. Writing reports summarizing study data	15	NA	NA	17	NA	NA
12. Developing standard operating procedures (SOPs)	20	23	9	15	21	8
13. Performing quality assurance of study activities for your site	19	11	10	17	20	8
14. Historical events in clinical research and development of research regulations	11	13	8	15	21	8
15.Learning about clinical research/Types of study designs	15	14	10	15	20	9
16.Process of drug and medical device development	NA	7	7	NA	17	9
17. Preparing for a monitoring visit.	NA	16	9	NA	19	8
18. Roles and responsibilities of study site personnel	NA	20	10	NA	7	6
19. Roles and responsibilities of study sponsors	NA	15	9	NA	17	8
20. Research ethics and scientific conduct	NA	20	10	15	19	8
21. Cultural issues in study participant recruitment	NA	15	10	17	19	8
22. Cultural issues and logistical issues impacting low resource study sites	NA	20	7	NA	16	9
23. Community involvement in clinical studies	NA	16	10	NA	19	8
24. Working with U.S. Federal sponsors and regulatory agencies	NA	16	9	NA	18	8
25. Basic overview of statistics with study methodologies	NA	22	5	NA	15	11
26. Study protocol development and approval processes	NA	24	6	NA	17	8
27. How a clinical study is planned and implemented at the	NA	20	6	NA	18	9

site						
28. Time management for study coordinators	NA	24	8	NA	17	8
29. Adverse event reporting and data safety monitoring board reviews	NA	20	9	NA	20	8
30. Challenges of international research in low resource countries	NA	11	9	NA	18	8

Course Development and Evaluation

HPTN-Supported Course

The HPTN course was offered as a 4-credit graduate level academic course, using the WebCT distance-learning platform. Three credits of the 4-credit course were devoted to didactic content, and 1 credit was devoted to a practicum component in which students applied principles from the course to a project in their own clinical settings. Students with a baccalaureate degree were awarded academic credit and those without a baccalaureate received “audit” credit.

We used a variety of teaching strategies that reflected the concepts included in the framework proposed by Lock and Redmond.[1] To *develop and maintain a teaching presence* we first provided students with an extensive module to help them learn to use the online technology and navigate the course. This orientation was critical because many students had no previous access with distance education. The orientation included a videotaped introduction of the course instructors in which the instructors introduced themselves, described their personal and professional backgrounds, and discussed the goals and teaching methods planned for the course. The instructors encouraged students to contact them via E-mail, telephone, or using internet chat technologies at any time throughout the course. The WebCT platform was used to deliver course content and promote communication between course participants and faculty . In addition, each participant received a CD-ROM that included all course content materials so they would have access to these materials even if their internet access was limited. We also provided course binders with hard copies of all course materials to facilitate access for students who had limited computer access.

Each module included a narrated PowerPoint lecture that was developed using Impatica for PowerPoint software, and a Microsoft Word document providing a typed narrative so that participants could both hear and read lectures. Relevant articles were included as PDF documents after copyright permission was granted by journal editors. We provided participants with two textbooks. One text included a basic overview of study coordination and good clinical practice guidelines.[27] The second text included consensus statements on the issues and ethical

regulations surrounding international clinical research in low-resource countries.[28] Student assignments included reading, writing and discussion activities designed to promote active learning and application of critical information to daily study coordination activities and problem issues.

To create and sustain a learning community we used discussion board postings, E-mail, and promotion of group learning projects. When participants had difficulty accessing the WebCT communication platform, they also used E-mail outside of the course to communicate with other students and with faculty.

Scaffolding learning principles were also incorporated into the course by organizing the course into nine separate modules that built upon one another. The course included content related to scientific integrity, ethics, informed consent, management and implementation of research consistent within specific cultural contexts, and principles of best practice. Table 2 lists the content that was included in the nine course modules.

Table 2

HPTN Course Content

Unit 1 (Overview of Historical, Ethical and Cultural Issues in Clinical Research)	**Unit 2 (Overview of Research Methods and Regulatory Processes in Clinical Research)**	**Unit 3 (Overview of Clinical Research Site Operations and Management)**
Module 1 - Historical and ethical Issues leading to Belmont Report, Declaration of Helsinki	**Module 1** - Introduction to experimental and non-experimental designs, reviewing different types of studies and statistical methods	**Module 1** - New Drug and Device Approvals, Sponsor and Site roles, Study initiation processes, recruitment and informed consent
Module 2 - Overview of Good Clinical Practice Guidelines (GCPs) and global clinical trials	**Module 2** - Qualitative verses Quantitative methods, reviewing research publications, identifying threats to validity, statistical issues in clinical trials and randomization	**Module 2** - Overview of data quality and monitoring
Module 3 - Defining and resolving issues related to scientific misconduct, conflicts of interest and participant confidentiality	**Module 3** - Overview of regulatory requirements, approvals and document management	**Module 3** - Site organization and management, developing and implementing standard operating procedures, quality assurance at the site.

To *create knowledge in action* we required all participants to develop a project in their clinical settings that reflected an application of course content. Examples of these projects included development of papers on topics such as participant recruitment and retention, or development and implementation of standard operating procedures. Eight of these projects were subsequently published in peer-reviewed journals.[29-36]

We used several approaches to foster a *social presence*. At the beginning of the course students developed PowerPoint presentations to introduce themselves and describe their goals for the course. *Social presence* and *critical discourse* were fostered by the use of E-mails, internet-based chats, and frequent posting of discussion board comments in response to course assignments. Fifty percent of the student grade was based on discussion comments that were evaluated using a structured rubric. Despite cultural, language and time-zone barriers, students participated actively in course discussions and many elected to complete their assignments with coordinators at other sites, thus providing multiple opportunities for collaborative learning. Students could select from a range of assignment topics to allow flexibility for the achievement of personal as well as course objectives.

Cognitive presence was fostered by establishing clear timelines and requirements for completing course activities and assignments. Learning was assessed through evaluation of discussion board postings using a structured rubric, grading of written assignments and project reports, and comparison of pre- and post-test scores on a multiple-choice test.

All course participants completed a structured course and teaching effectiveness evaluation at the end of the course, rating items on a 5-point scale with lower scores reflecting more positive evaluations. The mean rating for the 18 items on the teaching effectiveness scale ranged from 1.1 to 1.6. The mean ratings on the 13 items on the course evaluation scale ranged from 1.1 to 2.4 with a mean rating of 1.3 on the item reflecting participants' overall level of satisfaction with the course. Narrative comments indicated that the participants valued the opportunity to learn from other study coordinators across the globe, and that they viewed the course as extremely helpful. Another positive outcome of this course was that six of the students who took the HPTN course published papers that were developed as extensions of course assignments.[29-32,34,36] The main problem that participants identified was the difficulty finding time to complete requirements for this 4-credit course within the 15-week semester.

ICER- and CIDRZ-Supported Courses

The ICER- and CIDRZ-supported courses were developed as three individual continuing education (rather than academic credit) courses based on evaluation data from the HPTN course. We converted the four-credit course to three separate courses (two 1-credit courses, and one 2-credit course), offered over a

9-month period. In this way, each coordinator was expected to devote about 6 hours per week to course requirements. We converted the HPTN Course Units 1 and 2 to two separate courses each equivalent to 1 continuing education unit (or 15 contact hour units) (NUR 682 and NUR 683). We converted Unit 3 to a third course equivalent to 2 continuing education units (or 30 contact hour units (NUR 684). We offered all courses for continuing education rather than academic credit, thus eliminating strict requirements for admission of students to the University system and other administrative costs. Upon completing the three courses, participants received a certificate in clinical research.

The Web-CT distance-education platform was not used in the ICER and CIDRZ courses because of limited internet and computer access and funding limitations. Instead of using the Web-CT platform, we provided participants with notebooks and CD-ROMs (including objectives, assignments, narrated PowerPoint presentations, typed lecture notes, and articles for each module). We used E-mail and Skype chat technology to facilitate interactions between course faculty and participants and for online discussion forums of course topics. Because of language differences, we generally used typed Skype chats rather than voice chats. We provided written archives of the chats to all participants. Although the basic content from the HPTN course was maintained in the three ICER and CIDRZ courses, we updated the modules and modified the assignments and evaluation strategies based on feedback from the original course. We used similar teaching strategies used in the HPTN course to incorporate the concepts and principles identified by Lock and Redmond.[1]

As in the HPTN course, all ICER and CIDRZ course participants completed a 13-item course and an 18-item teaching effectiveness evaluation at the end of the course, rating items on a 5-point scale (1-5) with lower scores reflecting more positive evaluations. All mean scores were between 1-2, reflecting a high degree of satisfaction with both the courses and the teaching. Narrative comments indicated that the participants valued interaction with faculty and with other study coordinators across different sites, the opportunity to learn new content, and to apply it to their daily work, and the timely and constructive feedback from course faculty. Another positive outcome was the publication of papers based on course assignments by one of the ICER participants and one of the CIDRZ participants.[33,35]

The main problems identified by participants were problems with language (for participants from Mali for who French was the primary language), time constraints, and problems with internet access. Although some participants noted that problems with using the English language was sometimes a barrier, many expressed appreciation for the opportunity to improve their English skills by completing course requirements and receiving instructor feedback in English. Course participants expressed appreciation for the flexibility of the course, course content, and the ability to interact with clinical research colleagues from other countries. As in the HPTN course, we asked ICER participants to rate the

amount of time spent per week in the courses, and the response indicated that the average time involvement for each course averaged 6 to 10 hours per week.

ICER and CIDRZ-Funded Teaching Course

In order to develop capacity for ongoing research coordinator training at each site, we also developed and offered a 2-month online course in teaching strategies which was offered during the summer of 2007 to 13 coordinators who had completed the initial series of research coordination courses, and to others identified as having leadership potential who planned to enroll in the research courses during the 2007-2008 school year. The content of this teaching course included the following topics:

- Overview of basic principles and theories of teaching and learning
- Strategies of assessing learning needs
- Developing learning objectives
- Applying systematic approaches to designing an educational unit
- Identifying teaching strategies to achieve learning objectives
- Developing evaluation strategies appropriate for cognitive, affective and psychomotor learning
- Evaluating learning objectives
- Evaluating teaching, course and program effectiveness

Participants in the teaching course received 1 continuing education unit and a certificate upon completion of the course. They completed the 13-item course and 18-item teaching evaluation at the end of the course using the same 5-point Likert scale used in evaluations of the research coordination courses (with lower scores reflecting more positive evaluations). Mean scores were between 1-2, reflecting positive evaluations.

Following completion of the 2-month course, participants served as co-teachers and team leaders for the three research coordination courses offered during the 2007-2008 year and. Roles of co-teachers and team leaders included: (a) assisting in communication flow with the 2007-2008 course participants at the site level; (b) initiating training programs utilizing components from the ongoing course to clinical research staff who were not participating in the course; (c) organizing focus group discussions of course topics among course participants and others at the site; and (d) posting summaries of those discussions to all course participants to promote course community awareness and active discussion. Despite the lack of formal supervision, a collegial mentoring relationship was fostered and evaluation of the effort was favorable from actively participating co-teachers and team leaders who said that the role enhanced their appreciation of study coordinator course content and provided a platform to initiate discussions at the site on best practices.

Lessons Learned and Recommendations for Distance Based Education for Research Coordinators Internationally

The opportunity to develop training courses for study coordinators working in low-resource countries provided course instructors with an appreciation of the unique roles of study coordinators in today's complex world of global clinical trials, especially in low-resource southern hemisphere countries. Including coordinators from many different countries in the same courses provided a rich opportunity for both students and faculty to expand their understanding of cultural issues that influence all aspects of the research process, including participant recruitment, and retention, and even the definition of "who" the study participant is (e.g., the community as well as the individual). Course faculty members were impressed with the eager, respectful and compelling discussions among the course participants. Course evaluations and outcomes indicated that participants were empowered by the knowledge they gained and by the opportunity to participate in these courses. One example of this empowerment was the publication of seven papers to date by course participants that were developed by expanding on papers originally developed as course assignments.[29-36]

There were unique gender and cultural differences among the course participants that presented logistical challenges, but as sharing increased over time, the course community flourished. The co-teacher and team leaders helped to facilitate communication and creation of a learning community as they served as point-persons for instructors and led group discussions on course topics at their sites. Even though the course has long since ended, course participants continue to communicate via course list serves to share information and experiences or seek consultation about issues at their sites. This ongoing communication reflects the establishment of a true learning community within the courses.

There were some challenges to operating and teaching these courses that mirrored some of the barriers discussed by participants in their course evaluations. Managing the E-mail discussion postings in the ICER and CIDRZ courses (which were not offered on the WebCT online platform) was cumbersome and time-consuming, because all E-mails were sent to the faculty E-mail account rather than to a designated course E-mail account. We recommend that future distance courses use a designated distance-learning platform to facilitate communication and management of student assignments and learning activities.

Even though we provided the extensive orientation module, faculty also spent considerable time assisting students with technological issues because there was considerable variability in technical computer skills and equipment. Future courses should consider requiring a certain proficiency in the use of the distance technology prior to beginning the course.

Finally, there were challenges to communication based on differences in language, time-zones and cultural differences. Participants had competing priorities related to job and life responsibilities that sometimes made it difficult to devote time to completing course assignments. This problem was reduced when we converted the original 4-credit HPTN course to three separate courses for the ICER and CIDRZ coordinators, but even these coordinators experienced time pressures. Future offerings should ensure that course participants have appropriate release time from their job responsibilities or other support to ensure that they will have adequate time to devote to completing course requirements.

Our experience demonstrates that distance learning is an excellent strategy to provide education and build capacity for study coordinators globally. Including coordinators from diverse sites opens the door for sharing experiences from different settings, increasing understanding of cultural factors that influence all aspects of the research process, and developing sustainable learning communities that can enhance the quality of the research enterprise across the globe.

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